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NOTES

Mitochondrial Replacement Therapy: How a Government for the People, Failed the People

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Despite having the potential to significantly reduce the passage of many lethal diseases and devastating birth defects, mitochondrial replacement therapy—a controversial medical procedure in which mitochondrial RNA from a healthy female replaces the mitochondrial RNA from the intended mother in vitro—will have no place in the United States anytime soon. Under the guise of purported safety concerns and ethical dilemmas, the Republican Congress used its "power of the purse" to halt any and all research furthering mitochondrial replacement therapy, notwithstanding the fact that many leaders in the medical community have advocated for further research. Several developed countries have already implemented limited applications of the procedure. However, as long as Congress continues to abuse its constitutional appropriations power in a manner inconsistent with the original intent of the framers, policies that can greatly benefit society as a whole will be sacrificed in the name of partisanship and narrow-mindedness.

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INTRODUCTION

> *"We are on the cusp of being able to do [gene editing] safely, and the prospect of telling a parent that they won't have access to these therapies is morally untenable . . . A ban doesn't make sense . . . ."*[1]

Leo Chapman-Nesseth was born June 6, 2009 in Minnesota.[2] Described by his parents Andrew and Lindsay as "perfectly normal and healthy through the first six months of his life," Leo exhibited many of the conventional characteristics of a newborn: a pinkish color, ten fingers, ten toes, and a rambunctious personality.[3] At just eleven months old, Leo was diagnosed with Alpers' disease,[4] an autosomal recessive disease caused by a mutation in mitochondrial DNA with no cure and no method to slow its progression.[5] Leo quickly began to experience symptoms such as seizures and liver failure.[6] He died just three days after celebrating his first birthday.[7]

"Each year, 1,000 to 4,000 children in the United States are born with a mitochondrial disease."[8] Hope may be on the horizon, however, as doctors and researchers now believe that it may be possible to prevent the passage of mutated mitochondrial DNA from mothers to their offspring via a controversial technique still in the early

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[1] Alex Pearlman, *Scientists Argue the US Ban on Human Gene Editing Will Leave It Behind*, MOTHERBOARD (Aug. 4, 2016, 2:00 PM), https://motherboard.vice.com/en_us/article/nz7dp8/scientists-argue-the-us-ban-on-human-gene-editing-will-leave-it-behind (quoting bioethicist James Hughes, Executive Director of the Institute for Ethics and Emerging Technologies).

[2] Daily Globe News, *Family Raises Awareness for Rare Disease*, GLOBE (July 1, 2010, 9:49 PM), http://www.dglobe.com/news/1372692-family-raises-awareness-rare-disease.

[3] *Id.*

[4] *Id.*; *Alpers' Disease Information Page*, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE, https://www.ninds.nih.gov/Disorders/All-Disorders/Al pers-Disease-Information-Page (last modified June 15, 2018).

[5] *Alpers' Disease Information Page*, *supra* note 4.

[6] Nidhi Subbaraman, *'3-Parent Babies' Could Eliminate Rare Diseases, but US Lawmakers Have Blocked the Technology*, BUZZFEED NEWS (Sept. 13, 2016, 9:02 AM), https://www.buzzfeed.com/nidhisubbaraman/mitochondrial-disease-congress?utm_term=.hcAjPeqYqW#.vpYrQ9YRYj.

[7] *Id.*

[8] *Frequently Asked Questions*, UNITED MITOCHONDRIAL DISEASE FOUND., http://www.umdf.org/faq-page-1/ (last visited Sept. 14, 2018).

stages of experimentation. This process is known as mitochondrial replacement therapy.[9] Despite the safety concerns[10] associated with any groundbreaking medical procedure, as well as the ethical dilemma that germline-modified offspring from three parents presents,[11] an expert panel of scientists and bioethicists from the National Academies of Sciences and Institute of Medicine concluded that it was ethically permissible to "go forward, but with caution" with limited experimentation of mitochondrial replacement techniques at this point.[12]

Unfortunately, any momentum that had progressed in transitioning towards human trials in mitochondrial replacement therapy was abruptly halted by Section 749 of the Consolidated Appropriation Act of 2016, which precludes the Food and Drug Administration ("FDA") from evaluating any "research in which a human embryo is intentionally created or modified to include a heritable genetic modification."[13] In short, the largely Republican[14] Congress precluded the FDA from pursuing what could be a potentially life-saving technology for future generations.[15] It will now be seemingly

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[9] Eli Y. Adashi & Glenn Cohen, *Mitochondrial Replacement Therapy: Unmade in the USA*, 317 JAMA 574, 574–75 (2017), https://jamanetwork.com/ journals/jama/fullarticle/2601488.

[10] *Id.* at 574 (noting that safety concerns surrounding mitochondrial replacement therapy include possible mismatches between donors and recipients of Mitochondrial DNA, as well as the possibility that some of the mutated Mitochondrial DNA at issue may be transferred which would result in disease as well).

[11] *Id.* at 575.

[12] Joel Achenbach, *Ethicists Approve '3 Parent' Embryos to Stop Diseases, but Congressional Ban Remains*, WASH. POST (Feb. 3, 2016), https://www.washingtonpost.com/news/speaking-of-science/wp/2016/02/03/to-prevent-disease-ethicists-approve-creation-of-embryos-with-three-genetic-parents/?utm_term =.ccc4a92b133e (quoting chairman Jeffrey Kahn, bioethicist at John Hopkins University); *see* INST. OF MED., THE NAT'L ACADEMIES OF SCI., ENG'G & MED., REPORT IN BRIEF OF MITOCHONDRIAL REPLACEMENT TECHNIQUES: ETHICAL, SOCIAL, AND POLICY CONSIDERATIONS (2016), http://www.nationalacademies.org /hmd/~/media/Files/Report%20Files/2016/Mitochondrial%20Replacement%20Techniques/MitoEthics-RIB.pdf.

[13] Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

[14] *2016 House Election Live Results*, 270TOWIN, https://www.270towin.com /2016-house-election-results-live/ (last visited Sept. 15, 2018) (showing House election results and Senate election results in 2016).

[15] Adashi & Cohen, *supra* note 9, at 574–75.

impossible for the FDA to eventually make a definitive ruling on the safety and efficacy of the procedure.[16] To muddy the waters even further, the congressional record is completely silent on the identity of the supporters of the ban, and the exact motives for including the ban in the budget bill remain uncertain.[17]

This Note will first outline exactly what mitochondrial replacement therapy is and what experimentation of this technique entails. Part II will discuss the history and purpose of the Constitution's Appropriations Clause, demonstrating its clear potential for abuse and potential violation of the separation of powers doctrine. Part III will then illustrate historical Republican opposition and hostility towards disruptions with the natural birth cycle in support of my hypothesis, beginning with abortion and continuing with in vitro fertilization ("IVF") and stem-cell research. Part IV will then provide a recommended resolution between the FDA and Congress upon renewal of the budget bill in 2018.

I. MITOCHONDRIAL DISEASE: THE DIAGNOSIS, THE TREATMENT, AND THE IMPLICATIONS

A. *What Is Mitochondrial Disease and Whom Does It Affect?*

Mitochondria are organelles that are responsible for producing energy within cells in order for the cells to function properly.[18] Mitochondria also contain a small amount of genetic material—their own DNA—distinct from the DNA that is ordinarily found in a cell's nucleus.[19] Mitochondrial DNA is thus passed down from a mother to her child, and any mutations that occur in the mitochondrial genome can in turn lead to a plethora of mitochondrial diseases

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[16] Achenbach, *supra* note 12.

[17] Adashi & Cohen, *supra* note 9, at 574–75.

[18] Mike Orcutt, *The Unintended Consequence of Congress's Ban on Designer Babies*, MIT TECH. REV. (Aug. 26, 2016), https://www.technologyreview.com/s/602219/the-unintended-consequence-of-congresss-ban-on-designer-babies/#comments.

[19] *Id.*; *see also Advisory on Legal Restrictions on the Use of Mitochondrial Replacement Techniques to Introduce Donor Mitochondria into Reproductive Cells Intended for Transfer into a Human Recipient*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/ucm570185.htm (last updated Mar. 16, 2018) [hereinafter *Advisory*].

ranging in severity from relatively mild to potentially life-threatening.[20] Because mitochondria are the primary sources of energy production for all cells in the body, mitochondrial diseases typically manifest in tissues that rely heavily on energy production, including brain, heart, muscle, pancreas, and kidney cells.[21] As many as 4,000 children are born with mitochondrial diseases in the United States every year, and there are no licensed cures or treatments for these debilitating diseases.[22]

B. *How Can Mitochondrial Replacement Therapy Prevent Mitochondrial Disease?*

Although mitochondrial disorders are believed to be incurable per se, researchers now believe that it may be possible to prevent them from occurring at all through mitochondrial replacement therapy.[23] Mitochondrial replacement therapy is the "combining [of] the nucleus from the egg of an affected woman with the cytoplasm from an unaffected woman that contains healthy mitochondria."[24]

Dr. Shoukhrat Mitalipov, Director of Oregon Health and Science University's Center for Embryonic Cell and Gene Therapy, has demonstrated "in monkeys that a replacement mitochondrial genome from another mother can be effectively and safely passed to offspring along with the nuclear DNA from the actual mother."[25] Mitalipov had been working closely with the FDA in order to develop future plans for human testing of mitochondrial replacement therapy prior to the passage of the Consolidated Appropriation Act

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[20] *See* Gretchen Vogel, *For Boys Only? Panel Endorses Mitochondrial Therapy, but Says Start with Male Embryos*, SCI. (Feb. 3, 2016, 2:00 PM), http://www.sciencemag.org/news/2016/02/boys-only-panel-endorses-mitochondrial-therapy-says-start-male-embryos [hereinafter Vogel, *For Boys Only?*] ("Males can't pass along the mitochondrial DNA that is altered in the procedure . . . . Mitochondria] carry their own DNA, coding for 37 genes, which is passed down from *mother* to child through the mitochondria in the egg cytoplasm.") (emphasis added).

[21] DANIELA BARBERY ET AL., SHOULD THE U.S. APPROVE MITOCHONDRIAL REPLACEMENT THERAPY? 8 (2015).

[22] Orcutt, *supra* note 18.

[23] Adashi & Cohen, *supra* note 9, at 574.

[24] *Id.*

[25] Orcutt, *supra* note 18.

of 2016.[26] Mitalipov and his colleagues have also demonstrated that this "three parent" approach through the use of IVF of human embryos is medically feasible.[27]

C. *The Social and Ethical Concerns of Mitochondrial Replacement Therapy: How Do We Get There?*

Although mitochondrial replacement therapy could one day emerge as the exclusive method to allow women with mitochondrial diseases to have healthy children, the experimental method is certainly not without social and ethical challenges.[28] Though it would be a stretch to say doctors and scientists are, in fact, "play[ing] God,"[29] it is feasible to sympathize with those who are uncomfortable with the idea of scientists modifying human germlines. Some fear mitochondrial replacement therapy may be the first step in one day allowing a market for "designer babies" to flourish.[30]

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[26] *Id.*; *see* Consolidated Appropriations Act, 2016, Pub. L. 114-113, 129 Stat. 2242 (2015).

[27] Orcutt, *supra* note 18.

[28] *See generally* Ian Sample, *'Three-Parent' Babies Explained: What Are the Concerns and Are They Justified?*, GUARDIAN (Feb. 2, 2015, 10:56 AM), https://www.theguardian.com/science/2015/feb/02/three-parent-babies-explained (discussing various ethical and religious objections scientists and others have raised regarding the procedure).

[29] John D. Loike & Nancy Reame, *Opinion: Ethical Considerations of "Three-Parent" Babies*, SCIENTIST (Dec. 22, 2016), https://www.the-scientist.com/?articles.view/articleNo/47725/title/Opinion--Ethical-Consideratio ns-of--Three-Parent--Babies/ (discussing the dilemma scientists researching mitochondrial replacement therapy face due to the popular belief that genetic modifications are akin to "play[ing] God"). Loike and Reame note, however, that "humans have engaged in genetic modifications of plants and animals for thousands of years" without any ethical roadblocks, and are further engaged in a form of genetic screening known as preimplantation genetic diagnosis ("PGD"), which allows couples engaging in IVF to "screen" embryos for selection by eliminating those that possess various genetic diseases. *Id.*

[30] *See* Pam Belluck, *Gene Editing for 'Designer Babies'? Highly Unlikely, Scientists Say*, N.Y. TIMES (Aug. 4, 2017), https://www.nytimes.com/2017/08/04/science/gene-editing-embryos-designer-babies.html. Belluck notes that with modern-day science being one-step closer to repairing single gene mutations and defects in order to bypass serious or even fatal diseases, it may mean that we are also closer to "customizing" babies with "Lin-Manuel Miranda's imagination or Usain Bolt's speed." *Id.* This is misplaced for a variety of scientific reasons, however, discussed in detail in the article. *See id.*

Scientists in support of mitochondrial replacement therapy rebut these assertions, however, by pointing out that mitochondrial replacement therapy is more akin to various forms of preventative care, such as preimplantation genetic diagnosis of embryos to screen for genetic diseases, as opposed to individual gene shopping.[31] Furthermore, Philip Yeske, Science and Alliance Officer for the United Mitochondrial Disease Foundation, points out that only a very narrow population—"women of childbearing age who have mitochondrial disorders and who want to have children"—stand to benefit from the experimental technique in the first place; therefore, it is not akin to making designer babies or selecting genetic traits.[32]

The unintended social and legal consequences that may stem from "three-parent babies" are a second ethical roadblock for scientists and policymakers.[33] The term "three-parent babies" has grown to be frequently associated with mitochondrial replacement therapy due to the nature of the procedure, which involves contributions from three individuals: (1) the nucleus from the egg of an affected mother, (2) the cytoplasm from an unaffected woman that contains healthy mitochondria, and (3) the sperm of the father.[34] Because the nature of the procedure is seen as so fundamentally unconventional compared to how the average couple would go about having a child, it has led many to question how mitochondrial donation should be regulated in regards to legal issues such as parental rights, as well as

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[31] *See* Sample, *supra* note 28 (emphasizing that a change in law to allow mitochondrial replacement therapy research to continue would *not* allow "designer babies" to come about because the typical defining human characteristic traits such as eye and hair color are controlled by DNA in the cell nucleus, not the cell's mitochondria).

[32] Orcutt, *supra* note 18. Yeske notes that scientists researching mitochondrial replacement therapy "don't feel it's a slippery slope at all," due to the narrow target recipients of the procedure in the first place. *Id.*

[33] *See* Sample, *supra* note 28 (note that the graphic entitled "[t]hree-person embryos" outlines the two prominent mitochondrial replacement therapy techniques—maternal spindle transfer and pronuclear transfer—in which DNA from three different individuals is utilized in the creation of the embryo).

[34] *See* Adashi & Cohen, *supra* note 9, at 574; César Palacios-González, *Mitochondrial Replacement Techniques: Egg Donation, Genealogy and Eugenics*, 34 MONASH BIOETHICS REV. 37, 38 (2016).

whether the resulting offspring have a legal right to know their true lines of ancestry.[35]

This concern, although valid and well placed, is largely overblown for several reasons. First, from a practical standpoint, the mitochondrial DNA donation would come from an anonymous donor who has no legal rights over the child and is not involved in the child's upbringing in any way.[36] Therefore, as is the case with other reproductive technologies involving third parties such as oocyte donation and gestational surrogacy, mitochondrial replacement therapy is likely capable of establishing similar legal methods that in fact *protect* donor privacy.[37] From a strictly scientific standpoint, this argument lacks muster as well because all 20,000 genes located on the child's twenty-three pairs of chromosomes would still come from the child's intended mother and father.[38] The DNA contributed by the donor woman, which sits in the mitochondria, would constitute less than 0.2% of the child's DNA profile.[39]

II. THE BAN ON MITOCHONDRIAL REPLACEMENT THERAPY: HOW CONGRESS HAS HELD THE FDA HOSTAGE THROUGH THE APPROPRIATIONS CLAUSE

Although the benefits that mitochondrial replacement therapy would have for women susceptible to passing along mitochondrial diseases to their offspring are obvious, a congressional ban stands in the way of anyone actually receiving these benefits. Congress disabled the FDA's authority on the matter and swiftly put an end to all

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[35] *See* Loike & Reame, *supra* note 29. Loike proposes that because genetic contributions from mitochondrial DNA of a donor is essential for the development of the child, that genetic contribution from mitochondrial DNA should *not* be considered irrelevant to the status of parenthood, but should follow an already established avenue of determining or relinquishing parental rights, such as the system in place for adoption. *Id.*

[36] Sample, *supra* note 28.

[37] Loike & Reame, *supra* note 29 ("Given its potential for permanent alterations of DNA, this technology should not be viewed as equivalent to classical organ donation, but rather treated with precautions in line with other germline interventions, such as egg or sperm donation, for which regulatory practices are already in place. Using these as a framework, governments and the scientific community should invest time and money into making [mitochondrial replacement therapy] widely available to patients.").

[38] *See* Sample, *supra* note 28.

[39] *Id.*

mitochondrial replacement therapy research in the United States with nothing more than a ten-line provision in Section 749 of the Consolidated Appropriations Act of 2016.[40]

Despite the United Kingdom's approval in February 2015 of the technology,[41] the United States Congress was able to successfully shut down this research notwithstanding much opposition and hostility from scientists, doctors, and patients throughout the country.[42] As Dr. Shoukhrat Mitalipov has pointed out, despite the fact that the United States was "one of the pioneers" in developing mitochondrial replacement therapy,[43] clinical implementation of the procedure will only take place in other countries such as the United Kingdom.[44]

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[40] Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

[41] *See* Ewen Callaway, *Scientists Cheer Vote to Allow Three-Person Embryos*, NATURE (Feb. 3, 2015), http://www.nature.com/news/scientists-cheer-vote-to-allow-three-person-embryos-1.16843 (noting that the United Kingdom's House of Commons vote to legalize mitochondrial replacement therapy by a vote of 382 to 128 allows the United Kingdom to become the first country in the world to allow clinical applications of mitochondrial replacement therapy).

[42] *See* Subbaraman, *supra* note 6. Eli Adashi, Professor of Medical Science at Brown University, described the ban as "something unusual, perhaps *disturbing*, about Congress laying down the law when the scientific community and public are just beginning to understand the issue." *Id.* (emphasis added). Lindsay Chapman, an advocate of mitochondrial replacement therapy after losing her son Leo to Alpers' Disease in 2010, has said that she "can't even fathom why they would think that that would be something we shouldn't be researching and frankly, doing clinical trials on . . . There's just something inside of me that screams at the idea that somebody else would stand in the way." *Id.*; *see supra* note 2 and accompanying text. Philip Yeske stated "[t]hey were very clear in their report – they saw no ethical reason to limit human clinical studies for mitochondrial replacement therapy." Subbaraman, *supra* note 6.

[43] *Id.*

[44] *See* Rosa J. Castro, *Mitochondrial Replacement Therapy: The UK and US Regulatory Landscapes*, J.L. & BIOSCIENCES 726, 735 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5570689/pdf/lsw051.pdf ("The different stances of the UK and the USA with regard to MRT can probably be explained as the result of a combination of (i) historical events, including the adverse reports from cytoplasmic transfer treatments in the USA, (ii) the lack of a broader dialogue with experts and the public, (iii) the lack of a specialized authority in charge of reproductive technologies, and (iv) the deeply polarized abortion and 'personhood' debates.").

Congress was able to implement the ban effectively because the federal legislature potentially possesses the most powerful tool of any of the three branches of government: the power of the purse.[45]

A. *The Appropriations Clause: "The Power of the Purse"*

The federal legislature's appropriations power stems specifically from Article I, Section 9 of the Constitution. The Appropriations Clause states the following: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law; and a regular Statement and Account of the Receipts and Expenditures of all public Money shall be published from time to time."[46] In essence, for the executive branch and any federal agencies to act in order to achieve their goals and policies, Congress must affirmatively authorize the funds required for these projects.[47]

In the case of mitochondrial replacement therapy, the FDA is the federal agency seeking congressional appropriation of federal funding. The clinical use of mitochondrial replacement therapy in the United States falls within the FDA's regulatory authority because the FDA's oversight includes ensuring safe transfers of human cells and tissues into human recipients.[48] This includes the transfer of reproductive cells and tissues used in mitochondrial replacement therapy when mitochondria from a donor woman are transferred into the cells of a woman at risk for passing along mitochondrial disease traits.[49] Therefore, since Congress included provisions in Section 749 of the Consolidated Appropriations Act of 2016 that prohibit

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[45] "[T]he Constitution's most *significant* check on Executive power: the President can spend funds on a program *only if* he can convince Congress to appropriate the money." Kate Stith, *Congress' Power of the Purse*, 97 YALE L.J. 1343, 1350 (1988) (emphasis added) (citation omitted). "Among the duties—and among the rights, too—of this House, there is perhaps *none so important* as the control which it constitutionally possesses over the public purse." *Id.* (emphasis added) (citation omitted).

[46] U.S. CONST. art. I, § 9, cl. 7.

[47] *See* Stith, *supra* note 45, at 1350.

[48] *Advisory*, *supra* note 19. "The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research regulates an array of diverse and complex biological products . . . including human cell and gene therapy products and human cells and tissues. FDA's oversight includes ensuring that human cells and tissues intended for transfer into a human recipient, including reproductive cells and tissues, are free from infectious diseases." *Id.*

[49] *Id.*

the FDA from even accepting applications for clinical research involving gene editing in humans, clinical research of mitochondrial replacement therapy in humans cannot legally proceed in the United States at this time.[50] This holds true even if the source of funding for these experiments is from private third parties. The Consolidated Appropriations Act of 2016 prohibits the use of *any* federal funds to handle applications for the experiments.[51] The FDA is "disabled" from approving anyone to conduct experiments, even if they were able to secure funding on their own.[52]

The appropriations requirement imposed on the executive branch by the legislature is necessary because if Congress could not prohibit federal agencies from withdrawing funds from the Treasury, the executive branch could essentially compel its own legislation by spending money at will in order to push its own policies.[53] The Framers' intent, according to James Madison, was to assure that "the [legislature] alone ha[d] access to the pockets of the people."[54] What frustrates this issue even further, however, is that it has never been seriously proposed or alleged that Congress would, or even *could*, "violate" the Appropriations Clause by failing to effectively exercise control over federal expenditures.[55] Notwithstanding

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[50] *Id.*

[51] *See* Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

[52] *See* Achenbach, *supra* note 12 ("The omnibus fiscal 2016 budget bill passed by Congress late last year contained language prohibiting the government from using any funds to handle applications for experiments that genetically alter human embryos."). Dr. Shoukhrat Mitalipov described the function of the ban as follows: "It seems like the FDA is *disabled* in this case by Congress . . . . At this point we're still not clear how to proceed." *Id.* (emphasis added).

[53] *See* Stith, *supra* note 45, at 1349.

[54] Abner J. Mikva, *Congress: The Purse, the Purpose, and the Power*, 21 GA. L. REV. 1, 3 (1986) (citing THE FEDERALIST No. 48, at 334 (James Madison) (J. Cooke ed., 1961)).

[55] Stith, *supra* note 45, at 1344–45. Stith discusses the general assumption by constitutional scholars that "Congress has exclusive authority to construe and implement the appropriations clause," yet no one has really ever "considered the possibility that Congress itself may violate the clause." *Id.* at 1345 n.5. *But see* Dick Cheney et al., *The Constitution and the Budget Process*, *in* CONSTITUTIONAL CONTROVERSIES 63, 95 (Robert A. Goldwin et al. eds., 1987) (suggesting that aspects of legislative budget practice are "not in keeping with . . . the spirit of the appropriations clause").

the diverse interpretations of the intended effect of the Appropriations Clause, it remains concrete that, as used today, the appropriations power allows Congress to dictate exactly how federal agencies allocate the amount of federal funding appropriated to them,[56] even in ways that are directly adverse to the executive branch or society as a whole.

B. *The Purpose of the Appropriations Power, as Intended by the Framers of the Constitution*

Based on the Framers' placement of the Appropriations Clause in Section 9 Article I, rather than in Section 8 with most other congressional powers and responsibilities, the appropriations requirement was arguably not meant to be a grant of affirmative power to shape policy or push a partisan agenda.[57] In practice, however, the appropriations power does more than allocate funding to specified agencies and projects. This power delineates the scope of congressionally authorized activities and forbids the progression of those activities Congress opposes.[58] Although this safeguard serves as a valuable tool to protect abuses of power and discretion by the executive branch and federal agencies, it simultaneously allows the legislature to abuse its own power by essentially vetoing policies that can greatly benefit society at large, such as mitochondrial replacement therapy.

The ideological premise behind Congress possessing sole authority to *affirmatively* dictate how all federal funds are allocated is seemingly at odds with the separation of powers doctrine. Baron de Montesquieu first popularized the doctrine of separation of powers as the best strategy to avoid tyranny—the *equal* constitutional dis-

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[56] *See* Stith, *supra* note 45, at 1353 ("These strings, or conditions of expenditure, constitute legislative prescriptions that *bind the operating arm of government*. Occasionally, conditions may be stated in an appropriations statute itself. For instance, an appropriations act may provide that '[n]o part of any appropriation contained in this Act shall be used . . . for publicity or propaganda purposes . . .' Alternatively, the appropriations act may require that the recipient federal agency allocate the amount appropriated among certain activities or in accordance with certain conditions." (emphasis added)).

[57] *See id.* at 1349.

[58] *See id.* at 1356.

tribution of power among three branches of government: a legislative branch, executive branch, and judicial branch.[59] Proponents of the Constitution relied on Montesquieu's theory in dividing the power of government equally among the three branches in a way best described by Abner J. Mikva: "Congress would manage the purse, the President would wield the sword, and the courts would exercise the power of review [to] protect individual liberties in the newly formed federal government."[60] In other words, the individuals comprising each branch should have the "necessary constitutional means and personal motives to *resist encroachment* of the others."[61] In reality, however, how is the executive branch expected to "wield its sword" effectively, if at all, if Congress is granted plenary authority to dictate when and how it does so?

The answer lies in an interpretation of the Constitution that the appropriations power was never meant to be used as a weapon that allows Congress to affirmatively push its own policies.[62] If the Framers truly intended the power of the purse to be the strongest and most effective of all governmental powers, then it would also mean that the Framers intended to give the legislative branch a significant advantage over the executive branch in regards to checks and balances.[63] As pointed out earlier, however, James Madison's works show that the overarching goals of the Constitution were to ensure that each branch possessed the necessary tools to *prevent* any encroachment or any one branch from being capable of overpowering

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[59] *See* Mikva, *supra* note 54, at 2.

[60] *Id.*

[61] *Id.* (quoting THE FEDERALIST NO. 51, at 349 (James Madison) (J. Cooke ed., 1961)).

[62] *See* Kate Stith, *supra* note 45, at 1348 ("While section 8 of article I enumerates the powers of the legislative branch, the appropriations clause in section 9 is *not* a grant of power. Rather, the appropriations clause affirmatively obligates Congress to exercise a power already in its possession.").

[63] *See* Mikva, *supra* note 54, at 1–3. Mikva argues that, because the appropriations power is far and away the most powerful and effectual tool in the arsenal of any of the three governmental branches, it must mean that the Framers of the Constitution actually *intended* for the legislative branch to truly be the most powerful governing branch of the three. *See id.* This is obviously at odds with the doctrine of separation of powers, but is a helpful argument in demonstrating just how far the legislature is able to stretch the appropriations power to push their own agenda.

another.[64] It may be inferred, then, that perhaps the appropriations power has been abused in a way that makes the legislature more powerful than the executive branch.

The discretionary power granted upon Congress to make budgetary decisions that shape social and fiscal policy is a necessary evil, because, in theory, no branch is better suited to consider the diverse interests of the people than the legislature elected *by* the people.[65] In order for this power to function properly and not run amuck with the separation of powers doctrine, however, it can be inferred that Congress' responsibility in appropriating funds to executive agencies should be based on whether or not said appropriations will benefit the *people*, not simply coincide with particular party lines.

C. *How Has Congress Used the Appropriations Clause to Push Policy in the Past?*

Although Congress' method of barring the FDA from reviewing any further applications for mitochondrial replacement therapy can be described as a questionable use of the appropriations power at best, this is hardly the first time that Congress has used the Appropriations Clause to advance partisan objectives.[66] In fact, Congress effectively ended the Vietnam War simply through the exercise of its appropriations power.[67]

In 1974 and 1975, once Congress had become convinced that the Vietnam War needed to end, Congress refused to appropriate the more than $500 million requested by President Gerald Ford to continue the war effort.[68] Therefore, the war came to a rather abrupt end because Congress' denial to continue funding the war essentially

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[64] *See id.* at 2.

[65] *Id.* at 4. Mikva believes that "[n]o institution is more willing–no institution is better able–to consider and accommodate the[] [diverse interests of its citizens] than the legislative branch. The Framers' decision to give budgetary power to Congress rested largely on this view." *Id.*

[66] *Id*. at 4–5.

[67] *Id.* Mikva discusses that for years leading up to the Vietnam War and throughout the war, Congress vehemently resisted the "costly and futile foreign venture." *Id.* at 4. Once Congress was completely convinced that the War had to stop, it simply refused to appropriate any more money to the effort, forcing cessation against the executive branch's wishes. *Id.* at 4–5.

[68] *Id.*

forced the cessation of hostilities.[69] In turn, the appropriations power authorized Congress to not only make a determination that the government cannot afford spending any more federal funds on a particular activity—in this case, the controversial war—but it also allowed Congress to make a determination that "the specified activity is no longer within the realm of authorized government actions."[70]

Unlike the rejection of mitochondrial replacement therapy, Congress' use of the appropriations power to end the Vietnam War is a paradigm of how the Framers *intended* the power to be used.[71] This is vastly different than the situation surrounding mitochondrial replacement therapy. The Vietnam War represented an issue that divided the entire country[72]—an issue that resulted in the death of approximately 58,000 U.S. soldiers.[73] Put another way, Congress' decision to take action had much less to do with accommodating political ideologies than it did with resolving issues that had significant detrimental impacts on many Americans.

In contrast, curing mitochondrial diseases that impact up to 4,000 children every year is hardly an issue dividing the people to the extent that a Congressional ban seems prudent. Furthermore, if the use of federal funds represented a financial issue, as opposed to a social policy issue, Congress could have simply barred the use of federal funds directly for research purposes but still allowed the

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[69] *Id.*

[70] Stith, *supra* note 45, at 1360–61.

[71] Mikva, *supra* note 54, at 4–5 ("The Framers' decision to give budgetary power to Congress rested largely on this view . . . . Clearly, the Framers believed that decisions directly affecting the pocketbooks of our people should be made by the governmental institution that is closest to them.").

[72] Stephen Zunes & Jesse Laird, *The US Anti-Vietnam War Movement (1964-1973)*, INT'L CTR. ON NONVIOLENT CONFLICT (Jan. 2010), https://www.nonviolent-conflict.org/the-us-anti-vietnam-war-movement-1964-1973/ ("The U.S. war in Vietnam triggered the most tenacious anti-war movement in U.S. history . . . . [H]undreds of thousands of young people became radicalized in a largely nonviolent, diverse and sometimes inchoate popular culture of war resistance, employing tactics ranging from comical street theatre to industrial sabotage.").

[73] *Vietnam War U.S. Military Fatal, Casualty Statistics*, U.S. NAT'L ARCHIVES & RECORDS ADMIN. (Dec. 20, 2017), https://www.archives.gov/ research/military/vietnam-war/casualty-statistics.html ("The Vietnam Conflict Extract Data File of the Defense Casualty Analysis System (DCAS) Extract Files contains records of 58,220 U.S. military fatal casualties of the Vietnam War.").

FDA to accept applications from clinical trials funded entirely by third party payers. The fact that the appropriations requirement is only a condition precedent to executive branch action supports the notion that it was never intended to be a grant of affirmative power. Instead, it was intended to be a *limitation* on the exercise of legislative power.[74]

III. AN AGE-OLD DEBATE: THE PARTISAN DIVIDE OVER ABORTION AND THE TRANSITION TOWARDS EMBRYOS

A. *Republican Opposition to Abortion*

Ever since the Supreme Court decided in *Roe v. Wade* to grant women a limited right to abortion,[75] a "culture war" between Republicans and Democrats has raged regarding "the status of life after conception and before birth."[76] Prior to *Roe*, abortion was criminalized by statute as homicide in some states.[77] *Roe* shifted the meaning of the term "abortion" from a medical term used by physicians to a "public and moral issue of nationwide concern"[78] that routinely sparks contextual debates regarding human nature and when life truly begins.[79] I, like others, hypothesize that the divide amongst

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[74] Stith, *supra* note 45, at 1349–50, 1350 n.28 ("Placement of the appropriations requirement in section 9 is consistent . . . with the dual intent of the framers both to limit the power of the executive branch and to restrain the federal government as a whole.").

[75] 410 U.S. 113 (1973).

[76] Janet L. Dolgin, *Surrounding Embryos: Biology, Ideology, and Politics*, 16 HEALTH MATRIX 27, 31 (2006) [hereinafter Dolgin, *Surrounding Embryos*]; *see* Robin Toner, *The Nation: To the Barricades; The Culture Wars, Part II*, N.Y. TIMES (Feb. 29, 2004), https://www.nytimes.com/2004/02/29/weekinreview/the-nation-to-the-barricades-the-culture-wars-part-ii.html. At the 1992 Republican National Convention, Patrick Buchanan referred to the "cultural war" for the "soul of America" between Presidential candidates Bill Clinton and George H.W. Bush centered around the ideological differences the two had on abortion. Toner, *supra*.

[77] Kayhan Parsi, *Metaphorical Imagination: The Moral and Legal Status of Fetuses and Embryos*, 2 DEPAUL J. HEALTH CARE L. 703, 716–17 (1999).

[78] KRISTIN LUKER, ABORTION AND THE POLITICS OF MOTHERHOOD 127 (Brian Barry & Samuel L. Popkin eds., 1984) (emphasis omitted).

[79] *See id.* at 158–91 (examining pro-life and pro-choice views); *see also* Dolgin, *Surrounding Embryos*, *supra* note 76, at 31 n.26 ("Luker reports that more people became part of the movement opposing abortion in the year following Jan. 22, 1973 (the day on which *Roe* was decided) *than in any other year before or after*." (emphasis added)) (citing LUKER, *supra* note 78, at 137).

party lines with regard to abortion is, or at least should be, identical to a divide on the issue of mitochondrial replacement therapy because both involve the manipulation of embryos, and the disruption of the natural fetal development process.[80]

Today more than ever, abortion remains a contentious issue that diverges significantly depending on what side of the partisan line one falls on.[81] In a recent survey conducted by Pew Research Center, sixty-five percent (65%) of Republicans felt that abortion should be illegal in all or at least most cases, while seventy-five percent (75%) of Democrats felt that abortion should be legal in most cases.[82] While pro-life advocates have often framed the divide over abortion to stand for much larger social debates regarding "moral values" and family structure,[83] the thrust of most Republicans' argument revolves around the personhood status of the fetus.[84] Pro-life advocates have long believed that fetuses and embryos deserve better treatment than if they were biological property or tissue of the mother because, although they are not "persons" in a strict legal sense, they are in fact along a developmental path towards *becoming* persons.[85] Put simply, due to their "potential" for personhood, fetuses have always deserved a certain moral and intrinsic status as being "part of the continuum of biological human life."[86] The strong desire by pro-life advocates to restrict abortion, due to the personhood of a fetus, is summarized effectively in a metaphor by Dr. Steven Maynard-Moody, Director of the Institute for Policy & Social Research at the University of Kansas as follows:

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[80] Corey Washington, *Mitochondrial Replacement Therapies: Between Abortion and Genetic Engineering*, SPARTAN IDEAS (June 3, 2014), http://spartanideas.msu.edu/2014/06/03/mitochondrial-replacement-therapies-between-abortion-and-genetic-engineering/.

[81] Hannah Fingerhut, *On Abortion, Persistent Divides Between – and Within – the Two Parties*, PEW RES. CTR. (July 7, 2017), http://www.pewresearch.org/fact-tank/2017/07/07/on-abortion-persistent-divides-between-and-within-the-two-parties-2/ (noting that "the partisan divide on abortion remains far more polarized than it was two decades ago").

[82] *See id.*

[83] *See* Janet L. Dolgin, *Embryonic Discourse: Abortion, Stem Cells, and Cloning*, 31 FLA. ST. U. L. REV. 101, 121–28 (2003) (discussing the broader social implications that stem from the abortion debate).

[84] *See* Dolgin, *Surrounding Embryos*, *supra* note 76, at 31–32.

[85] *See* Parsi, *supra* note 77, at 704.

[86] *Id.* at 705.

> [T]he fetus is not a spleen. Though wholly dependent on the pregnant woman and unable to live outside her womb, a not-yet-viable fetus is genetically distinct from the pregnant woman; it is not an organ or tissue, but a body, suggesting to some that it can be defined as a person . . . . The view that the fetus is tissue or tissue property is founded on complex scientific evidence about human development and legal arguments about torts and rights, whereas the image of the fetus as a baby is based on a simple, emotional reaction to the form: it looks like a baby.[87]

While the historical divide among partisan lines over abortion is not the focal point of the potential divide over mitochondrial replacement therapy, it is important to understand this divide because it represents the same partisan issue that has evolved as scientific research has improved: the legal and moral status of embryos.

B. *Republican Opposition to Embryonic and Stem-Cell Research*

With scientific improvements in the medical industry allowing us to see further and further down the line of fetal development,[88] the politicization of the debate regarding the personhood of a fetus began to evolve a similar politicization of the embryo.

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[87] STEVEN MAYNARD-MOODY, THE DILEMMA OF THE FETUS 86 (1995).

[88] *See* Dolgin, *Surrounding Embryos*, *supra* note 76, at 34–35 ("Embryos came into social consciousness as the result of medical and technological developments. The first among these developments was increasingly accurate and inexpensive pregnancy tests that could be used soon after conception, followed by the development of ultrasonography which permitted pregnant women, their partners, and their health care providers to visualize the progress of a pregnancy before the start of the fetal stage. The appearance of an industry in infertility care in the late 1970s and early 1980s played a major role in society's reconceptulization of the notion of embryo.").

When a male reproductive sperm cell fertilizes a female reproductive oocyte, or "egg," a new cell is formed known as a "zygote."[89] When the zygote cell begins to divide, it becomes an "embryo."[90] The mass of cells that has formed after fertilization continues to be considered an "embryo" until approximately the eighth week of development, at which point the embryo becomes a fetus.[91]

The fact that embryos are a cluster of cells—unlike fetuses, which more closely resemble babies—has made it difficult for the pro-life movement to muster the same strong argument for embryonic life as it could for fetal life.[92] Despite this, many Republicans[93] and other pro-life advocates such as the Catholic Church have staunchly opposed any scientific research efforts that ultimately result in the manipulation or destruction of embryos.[94]

The partisan divide over the philosophical definition of embryos is best highlighted by a juxtaposition of Democrat President Clinton's proposed guidelines on federal funding for stem cell research in 2000 with that of Republican President Bush's opposition in 2005. Shortly after "U.S. scientists successfully isolated and cultured stem cells obtained from human embryos and fetuses" in 1998, "President Clinton approved the National Institutes of Health's (NIH) proposed guidelines to allow federal funding for research on stem cells."[95] This federal funding allowed scientists to study the effects of introducing healthy stem cells into the body to potentially treat many diseases that are caused from the death of dysfunctional

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[89] *Egg to Embryo to Fetus: The Reproduction and Development Process*, VISIBLE BODY, https://www.visiblebody.com/learn/reproductive/reproductive-process (last visited Sept. 20, 2018) [hereinafter *Egg to Embryo to Fetus*].

[90] *Id.*; *see also* Simon Fishel, *Assisted Conception in the Human – The Embryological View*, *in* CONCEIVING THE EMBRYO: ETHICS, LAW, AND PRACTICE IN HUMAN EMBRYOLOGY 15 (Donald Evans & Neil Pickering eds., 1996) (noting that an embryo forms approximately twenty-four hours after fertilization).

[91] *Egg to Embryo to Fetus*, *supra* note 89.

[92] *See* Dolgin, *Surrounding Embryos*, *supra* note 76, at 35.

[93] *See infra* text accompanying notes 98–106.

[94] *See* Erin P. George, *The Stem Cell Debate: The Legal, Political and Ethical Issues Surrounding Federal Funding of Scientific Research on Human Embryos*, 12 ALB. L.J. SCI. & TECH. 747, 751 (2002) ("The Catholic Church is opposed to IVF because of the method used to collect semen, masturbation, and the fact that sexual intercourse is not the procreative function used.").

[95] *Id.* at 748.

cells.[96] In enthusiastic support of the emergence of stem cell capabilities, President Clinton commented that stem cell research offers "potentially staggering benefits,"[97] and scientists worldwide have commented on the potential benefits as well.[98] However, opposition to stem cell research often derives not from the potential benefits it provides, but from the process required to get there.[99] This process requires human stem cells to be extracted from human embryos anywhere from seven to fourteen days after fertilization occurs, thereby resulting in the death of the embryo.[100]

President Bush, on the other hand, strongly opposed all research using human embryos, and sought to promptly end all federal funding of stem cell research.[101] In 2005, after announcing that he intended to veto a pending bill that would allow federal funding for embryonic stem-cell research,[102] President Bush pledged to protect those who he deemed "our society's most vulnerable members."[103] Other prominent Republican figures have referred to proposed NIH guidelines on stem cell research as "a sham" that "attempt to give a glow of respectability to truly *barbaric* and *grotesque* experiments on human beings."[104] As recently as July 2016, the Republican platform has explicitly opposed and condemned embryonic stem cell research, announcing at the Republican Convention in July 2016:

> We oppose embryonic stem cell research. We oppose federal funding of embryonic stem cell research. We

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[96] *See id.* at 756.

[97] Gretchen Vogel, *NIH Allows Pluripotent Stem Cell Research*, SCI. (Aug. 23, 2000, 6:00 PM), http://www.sciencemag.org/news/2000/08/nih-allows-pluripotent-stem-cell-research [hereinafter Vogel, *NIH*].

[98] *See* George, *supra* note 94, at 758.

[99] *See id.* at 756.

[100] *See id.*

[101] *See id.* at 775.

[102] *See US Stem Cell Bill Stalls in Senate*, BIONEWS (July 24, 2005), https://www.bionews.org.uk/page_89755; *see also* Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2005).

[103] Press Release, President George W. Bush, President Discusses Embryo Adoption and Ethical Stem Cell Research (May 24, 2005), https://georgewbush-whitehouse.archives.gov/news/releases/2005/05/20050524-12.html.

[104] Susan Lee, Harvard Law & Health Care Soc'y, *Human Stem Cell Research: NIH Releases Draft Guidelines for Comment*, 28 J.L. MED. & ETHICS 81, 82 (2000) (quoting Representative Christopher Smith, a Republican from New Jersey) (emphasis added).

> support adult stem cell research and urge the restoration of the national placental stem cell bank created by President George H.W. Bush but abolished by his Democrat successor, President Bill Clinton. We oppose federal funding for harvesting embryos . . . .[105]

This statement sparked a response from Dr. George Q. Daley, a researcher at the Harvard Stem Cell Institute, who told Bloomberg BNA that human embryonic stem cells are "essential" for medical research, and that "[i]t would be a major setback should the Republican Party succeed in turning back the clock to a more restrictive stem cell policy."[106]

Even during the first debate of the 2016 Presidential campaign, Republican candidates disagreed on every single topic discussed except for one: research using fetal tissue cells.[107] Such a united front against any and all research involving the use of donated embryos represents a major hurdle for the scientific community towards improving health and saving lives, especially when bipartisan support is needed to secure federal funding or approval. The latest experimental breakthrough to fall victim to Republican opposition: mitochondrial replacement therapy.

C. *Why Opponents of Abortion and Embryo Research Are Likely Opposed to Mitochondrial Replacement Therapy*

Although virtually no literature currently discusses the division over mitochondrial replacement therapy from a political ideology standpoint, the similarities in mitochondrial replacement therapy research and stem cell research are clear. Therefore, the same partisan group who has historically opposed abortion and various forms of

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[105] *Republican Platform Blasts FDA, Seeks Embryonic Stem Cell Ban*, RES. AMERICA (July 20, 2016), http://www.researchamerica.org/news-events/news/republican-platform-blasts-fda-seeks-embryonic-stem-cell-ban.

[106] *Id.*

[107] Dov Fox, *The GOP Case Against Stem Cell Research*, HUFFINGTON POST (Aug. 7, 2015, 8:35 PM), https://www.huffingtonpost.com/dov-fox/gop-confusion-over-stem-c_b_7958424.html ("The [Republican candidates] disagreed on every topic they faced—immigration, health care, foreign policy, gay rights, the economy . . . . All 17 [candidates] in [the] debates . . . *staunchly* opposed research that uses tissue cells from aborted or miscarried fetuses." (emphasis added)).

embryonic research—the Republican Party—likely opposes mitochondrial replacement therapy experimentation as well. Because the early experimental stages of mitochondrial replacement therapy in human clinical trials would result in the destruction or discard of donated embryos, Republicans and pro-life groups are likely to equate the treatment of embryos in mitochondrial replacement therapy to the way embryos are destroyed during stem cell research.[108]

D. *Progress Towards and Success of Mitochondrial Replacement Therapy*

Recent evidence from the United States indicates that mitochondrial replacement therapy techniques are in fact *safe* and *effective* in primates.[109] However, further research is still necessary to determine both the safety and effectiveness in humans, as well as the long-term effects of mitochondrial replacement therapy.[110] In contrast, mitochondrial replacement therapy experimentation received extensive support in the United Kingdom and, in 2015, the United Kingdom Parliament voted to allow mitochondrial donation for the purposes of mitochondrial replacement therapy on a case-by-case basis.[111] Further, in September 2016, the world's first "three-parent baby" was born after successful use of the mitochondrial replacement technique by a United States-based team in Mexico.[112]

Although concerns regarding safety and effectiveness inevitably will remain, the successful application of the mitochondrial replacement therapy technique performed by Dr. John Zhang and his team from New Hope Fertility Center in New York is likely to fast-forward progress from other nations more inclined to accept this research.[113] This successful application involved a patient of Dr.

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[108] *See* George, *supra* note 94, at 756.

[109] *See* Orcutt, *supra* note 18.

[110] *UMDF Position & Clinical Status of Mitochondrial Replacement Therapy to Prevent Transmission of mtDNA Disease*, UNITED MITOCHONDRIAL DISEASE FOUND. (Nov. 2017), http://www.umdf.org/mitochondrial-replacement-therapy/.

[111] *Id.*

[112] Jessica Hamzelou, *Exclusive: World's First Baby Born with New "3 Parent" Technique*, NEW SCIENTIST (Sept. 27, 2016), https://www.newscientist.com/article/2107219-exclusive-worlds-first-baby-born-with-new-3-parent-technique/.

[113] *See id.* ("The controversial technique . . . has only been legally approved in the UK. But the birth of the child, whose Jordanian parents were treated by a

Zhang's who carries a gene for Leigh Syndrome, which is a fatal mitochondrial disorder that negates healthy development of the nervous system.[114] After Leigh Syndrome was passed down from the mother's mitochondrial DNA and killed their first two children, the couple sought out Dr. Zhang and his team to perform a variation of the mitochondrial replacement therapy known as "spindle nuclear transfer."[115] Dr. Zhang was able to create five embryos for the couple, one of which developed normally, and was implanted in the mother.[116] Nine months later, the child was born healthy, with less than one percent of his mitochondria carrying mutated mitochondrial DNA, far below the eighteen percent that is generally required before problems begin to arise.[117]

Furthermore, Dr. Zhang's approach was met with glowing remarks by colleagues in the field.[118] Most importantly, the team executed the mitochondrial replacement therapy without destroying a single embryo, and used only a male embryo so as to avoid any chance a resulting female child could later pass on any inherited mitochondrial DNA.[119] Dr. Sian Harding, Professor of Cardiac Pharmacology at the National Heart and Lung Institute,[120] stated that Dr. Zhang's work was "as good or better than what we'll do in the

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US-based team in Mexico, should fast-forward progress around the world, says embryologists.").

[114] *Id.*; *see also Leigh Syndrome*, U.S. NAT'L LIBRARY MEDICINE: GENETICS HOME REFERENCE (June 2016), https://ghr.nlm.nih.gov/condition/leigh-syndrome.

[115] *See* Hamzelou, *supra* note 111. Hamzelou notes that because of the couple's Muslim heritage, they were opposed to the destruction of what would be the resulting embryos. *Id.* Therefore, Zhang performed spindle nuclear transfer, whereby "[h]e removed the nucleus from one of the mother's eggs and inserted it into a donor egg that had had its own nucleus removed. The resulting egg – with nuclear DNA from the mother and mitochondrial DNA from a donor – was then fertilised with the father's sperm." *Id.*

[116] *Id.*

[117] *Id.*

[118] *See id.* ("The team seems to have taken an ethical approach with their technique, says Sian Harding."). Sian Harding is a Professor of Cardiac Pharmacology at the National Heart and Lung Institute. *Professor Sian Harding*, IMPERIAL LONDON C., https://www.imperial.ac.uk/people/sian.harding (last visited Sept. 22, 2018).

[119] Hamzelou, *supra* note 111.

[120] *Professor Sian Harding*, *supra* note 117.

UK."[121] It is a shame, however, that Dr. Zhang and his team had to perform the procedure in Mexico, as opposed to New York, in order to save this baby's life.[122]

IV. CONGRESS ABUSED ITS APPROPRIATIONS POWER IN ORDER TO PRECLUDE FURTHER RESEARCH ON MITOCHONDRIAL REPLACEMENT THERAPY

While it is understandable that Republican and pro-life opposition towards embryonic research would result in hesitation to quickly move forward from research in primates to research in humans, it was improper for Congress to bar clinical trials in the manner that it did. The preclusion of the FDA to review all public *and private* applications for mitochondrial replacement therapy research in an omnibus fiscal bill is a blatant misuse of the appropriations power afforded to Congress. Not only does it prevent society from receiving the large benefit the research would have, it also likely violates the separation of powers doctrine by infringing on authority that is rightfully afforded exclusively to the FDA.

A. *The Context Behind How the Ban Was Introduced Is Controversial and Concerning*

As argued previously, the Framers' intent in granting the appropriations power to the legislative branch was to give Congress no more authority than necessary to *manage*[123] the "purse" that is the federal treasury.[124] Although wielding wide discretion to appropriate, Congress' power was intended to be limited to the extent necessary to prevent abuses in spending by the executive branch and its agencies.[125] This was meant to serve as a guard against encroachment by the executive branch, not an affirmative weapon to controvert the executive branch.[126]

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121 Hamzelou, *supra* note 111.

122 *See id.* ("Neither method has been approved in the US, so Zhang went to Mexico instead, where he says 'there are no rules[.'] He is adamant that he made the right choice. 'To save lives is the ethical thing to do,' he says.").

123 *See* Mikva, *supra* note 54, at 2.

124 *See supra* Sections II.A., II.B.

125 *See id.*

126 *See id.*

The circumstances surrounding the ban encompassing mitochondrial replacement therapy are nothing short of suspicious. Congressional Republicans proposed the $1.1 trillion omnibus spending bill in a fashion that forced President Obama to sign the bill with little time to review because he faced the prospect of a complete government shut down.[127] The bill, which was over 2,000 pages in length,[128] contained a vast range of other appropriations that needed to be voted on in an "all-or-nothing"[129] fashion as part of the annual balancing of the federal budget process. Tucked away discreetly in a ten-line provision amidst this massive federal spending bill is the language that affirmatively preempts the FDA from evaluating mitochondrial replacement therapy research.[130] The congressional record is completely silent regarding the identities of the sponsors of the ban, as well as the precise motives for sneaking it into the bill in such a manner.[131] There was a "complete absence of discussion before its passage or at any time thereafter," despite being included "in a must-pass omnibus appropriation bill."[132] Dr. Eli Adashi has said that scientists and other advocates of the research have "no idea how the ban's language even came to be a part of the bill" and that "[t]here's no paper trail, there's no smoking gun—there is just the

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[127] Tanya Lewis, *Congress Just Put a Massive Roadblock in the Way of Genetically Editing Human Embryos*, BUS. INSIDER (Dec. 16, 2015, 2:45 PM), http://www.businessinsider.com/congress-bans-funding-for-embryo-gene-editing-2015-12.

[128] The bill contains 2,009 pages worth of appropriations and conditions. *See generally* H.R. RULES COMM., 114TH CONG., TEXT OF HOUSE AMENDMENT #1 TO THE SENATE AMENDMENT TO H.R. 2029, MILITARY CONSTRUCTION AND VETERANS AFFAIRS AND RELATED AGENCIES APPROPRIATIONS ACT, 2016 (Comm. Print. 2015).

[129] *See id.*; *see also* Lewis, *supra* note 126 ("[T]he spending bill also expands the National Institutes of Health's annual budget by $2 billion to a total of $32 billion, including $350 million for Alzheimer's research. In addition, the Food and Drug Administration will get an additional $133 million for a total of $2.7 billion, which includes additional funding for President Obama's Precision Medicine Initiative.").

[130] *See* Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

[131] Adashi & Cohen, *supra* note 9, at 575.

[132] *Id.*

result."[133] Even the Appropriations Committee spokesperson, Jennifer Hing, refused to comment on where the language came from when pressed on the issue by BuzzFeed in 2016.[134]

This series of events does not represent a legislative "check" on the executive branch's "wielding of its sword," as Baron de Montesquieu and James Madison intended in framing the separation of powers doctrine and the Constitution.[135] The FDA has served as a consumer protection agency since the congressional passage of the 1906 Pure Food and Drugs Act,[136] and possesses plenary authority to ensure that food, cosmetics, drugs and medical devices are medically and nutritionally sound.[137] By definition, the appropriations power does not explicitly grant the legislative branch authority to dictate how executive agencies enforce the law, yet that is seemingly what the condition attached to Section 749 of the Consolidated Appropriations Act of 2016 aimed to do by outlawing any reviews of applications for particular medical research.[138] Congress is authorized by the Constitution to deny appropriations, and quite frankly, should be encouraged to if federal funds are sought in an encroaching manner or for a particular activity that does not serve the best interests of the people. Reviewing clinical applications for privately funded medical research that can save thousands of lives every year, however, does not match that description.

B. *The Congressional Ban Was Just as Careless as It Was Purposeful*

There is no denying that the language of Section 749 of the Consolidated Appropriations Act of 2016, which prohibits the FDA from reviewing applications "in which a human embryo is intention-

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133 *See* Subbaraman, *supra* note 6.

134 *Id.*

135 *See supra* notes 54–56.

136 *See When and Why Was FDA Formed?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AboutFDA/Transparency/Basics/ucm214403.htm (last updated Aug. 22, 2018).

137 Ben Panko, *Where Did the FDA Come From, and What Does It Do?*, SMITHSONIAN.COM (Feb. 8, 2017), https://www.smithsonianmag.com/ science-nature/origins-FDA-what-does-it-do-180962054/.

138 *See* Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

ally created or modified to include a heritable genetic modification"[139] grounds any further research on mitochondrial replacement therapy in the United States for the time being. However, what if mitochondrial replacement therapy was not the intended target of the Republican Congress' misuse of the Appropriations Clause? Is careless crafting of a budget bill that handcuffs the FDA's administrative authority to regulate an area of scientific research any less damaging than a purposeful and sneaky effort to tuck such a divided and controversial provision into a colossal omnibus bill without any explanation for its inclusion?

Some experts in the field, such as Dr. Eli Adashi, believe that there is a strong likelihood that Congress' primary target was not, in fact, mitochondrial replacement therapy, but a more controversial genetic technology known as "CRISPR."[140] CRISPR technology is much more in line with the traditional fears held by Republicans and pro-life advocates that scientists will try and "play God"[141] by engineering "designer babies" through the direct manipulation of the human genomes.[142] CRISPR is significantly more controversial than mitochondrial replacement therapy because rather than swapping out already existing DNA with DNA from another person in order to prevent the passage of a disease, "CRISPR targets specific genes in the code to delete or 'edit,'" thus leading to the fear of future "designer babies."[143]

This contentious technology possesses the sort of social and ethical concerns that the Framers likely would have had in mind when giving the legislative branch authority to deny appropriations to executive agencies. Yet, the perhaps unintended consequence of the

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[139] *Id.*

[140] *See* Subbaraman, *supra* note 6.

[141] Loike & Reame, *supra* note 29.

[142] *See* Subbaraman, *supra* note 6; *see also Questions and Answers About CRISPR*, BROAD INST., https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/questions-and-answers-about-crispr (last visited Sept. 19, 2018) ("'CRISPR' (pronounced 'crisper') stands for Clustered Regularly Interspaced Short Palindromic Repeats, which are the hallmark of a bacterial defense system that forms the basis for CRISPR-Cas9 genome editing technology. In the field of genome engineering, the term 'CRISPR' or 'CRISPR-Cas9' is often used loosely to refer to the various CRISPR-Cas9 and -CPF1, (and other) systems that can be programmed to target specific stretches of genetic code and to edit DNA at precise locations, as well as for other purposes, such as for new diagnostic tools.").

[143] *See* Subbaraman, *supra* note 6.

way in which Congress drafted the budget bill in 2016 precluded not only CRISPR, but other areas of genetic research that do not pose vast ethical dilemmas and partisan divisions. It was very feasible at the time the bill was passed for the drafters of the bill to deny appropriations for FDA review of applications for CRISPR research, without simultaneously precluding mitochondrial replacement therapy research in the process.

Even if Congress' outright ban on genetic modification research on human embryos was aimed at CRISPR with good intentions, it was clearly ineffective and, quite frankly, unnecessary. Many scientists today are in agreement that testing CRISPR germline editing in humans is nothing short of ethically impermissible and "irresponsible at this point."[144] Furthermore, a global committee consisting of gene-editing experts and ethicists, which convened at the International Summit on Human Gene Editing in 2015 concluded that creating gene-modifications in humans cannot go forward until the safety is established and there is a "broad social consensus on whether such a step is desirable."[145] David Baltimore, a Nobel Prize-winning biologist at the California Institute of Technology, stated that "[t]he human genome is shared among all nations . . . . [Safety and social/ethical consensus] criteria have not been met for *any* proposed clinical use."[146]

If CRISPR was the target of the language in the bill, it was superfluous for Congress to seek to bar any research efforts of this type when the scientific community is seemingly in agreement that it is unsafe and unethical to further research efforts in the first place. Moreover, the way in which Congress chose to attack CRISPR was also imprudent and reckless because it barred further research on mitochondrial replacement therapy. Whether Congress purposefully targeted mitochondrial replacement therapy based on partisan viewpoints towards personhood and embryonic research or whether mitochondrial replacement therapy was an unintended casualty of an intended ban on CRISPR does not change the fact that Congress

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144 Orcutt, *supra* note 18.

145 Antonio Regalado, *Scientists on Gene-Edited Babies: It's "Irresponsible" For Now*, MIT TECH. REV. (Dec. 3, 2015), https://www.technologyreview.com/s/544161/scientists-on-gene-edited-babies-its-irresponsible-for-now/.

146 *Id.* (emphasis added).

abused its appropriations power in the process. Regardless of Congress' true intent, Congress did not trigger its appropriations power to prevent the executive branch from spending money at will and pushing its own policies and agenda, as the Framers originally intended the power to be used. Instead, Congress affirmatively barred a federal agency from reviewing applications for privately funded research that is safe, ethically permissible, and has the potential to help save thousands of lives.

V. FUTURE RECOURSE AND THE RECOMMENDED NEXT STEPS FOR THE FDA

As pointed out in Part I, to date, there has been no judicial enforcement of the Constitution's appropriations requirement against Congress itself,[147] and it is therefore unclear if and how Congress can even be found in *violation* of Article I, Section 9.[148] In fact, any judicial challenge to the spending authority of Congress is likely doomed based on the Supreme Court's indication that "Congress has absolute authority to construe and to effectuate the appropriations requirement."[149] While it is relatively clear that the executive branch violates the Appropriations Clause if it spends funds not appropriated by Congress or based on Congress' limitations, it is not entirely clear how Congress can be said to "violate" the Appropriations Clause. Such a violation would likely arise by legislating open-ended spending authority in areas in which the executive branch bears substantial discretionary power.[150]

A judicial challenge to the congressional ban on gene editing research involving human embryos is almost guaranteed to fail, based on the historical context in which the appropriations power has been construed.[151] In *United States v. Richardson*, the Supreme Court held that Congress has "plenary" authority to implement the

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147 *See* Jonathan Lurie & Michele Ferri, *The Appropriations Clause: A History of the Constitution's (As of Yet) Underused Clause*, SOLARI REPORT (Jan. 10, 2018), https://constitution.solari.com/the-appropriations-clause-a-history-of-the-constitutions-as-of-yet-underused-clause/#ch16; *see also* Stith, *supra* note 45, at 1392.

148 *See id.* at 1344–45 (emphasis added).

149 *Id.* at 1392.

150 *See* Stith, *supra* note 45, at 1386.

151 *See id.* at 1392.

very similar "Statement and Account" clause involving appropriations for the CIA.[152] In *Harrington v. Bush*, a congressman's challenge alleging that the CIA was using its secret appropriations for unauthorized activities was dismissed for lack of standing,[153] but not before the Court suggested that Congress has "plenary" authority to interpret Article I, Section 9, "including the appropriations clause, and that the courts therefore have no power to consider the constitutional adequacy of spending legislation."[154] Clearly, the Court has decided that the judicial branch is not positioned or constitutionally capable of definitively determining what role independent executive agencies should have in developing the federal budget.

This predicament does not foreclose the motive or opportunity the FDA, and others in the field, should have to lobby Congress for a much more specific bill that would allow mitochondrial replacement therapy research to go forward with caution. Although the all-encompassing language used in Section 749 of the Consolidated Appropriations Act of 2016 includes technologies like mitochondrial replacement therapy and CRISPR based on strict interpretation of the terminology used, the bill does not *specifically* ban "mitochondrial replacement therapy" or "CRISPR" by name.[155] Due to the fact that mitochondrial replacement therapy is only used to prevent the passage of heritable deadly mitochondrial diseases,[156] as well as the relative progress that has been demonstrated by research in other countries thus far,[157] it is not farfetched to suggest that Congress

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[152] *Id.* (citing United States v. Richardson, 418 U.S. 166, 178 n.11 (1974)) ("[I]t is clear that Congress has *plenary* power to exact any reporting and accounting it considers appropriate in the public interest." (emphasis added)).

[153] *Id.* (citing Harrington v. Bush, 553 F.2d 190 (D.C. Cir. 1977)).

[154] *Id.*

[155] *See* Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 749, 129 Stat. 2242, 2283 (2015) (explicitly precluding the FDA from evaluating any "research in which a human embryo is intentionally created or modified to include heritable genetic modification," but not specifically mentioning mitochondrial replacement therapy or CRISPR).

[156] *See* Adashi & Cohen, *supra* note 9, at 574 (highlighting that mitochondrial replacement therapy "takes aim" at "maternally inherited mitochondrial diseases" for "risk reduction treatment").

[157] *See* Castro, *supra* note 44 ("The different stances of the UK and the USA with regard to MRT can probably be explained as the result of a combination of (i) historical events, including the adverse reports from cytoplasmic transfer treatments in the USA, (ii) the lack of a broader dialogue with experts and the public,

may be receptive to legislation that creates a narrow, specific exception to Section 749 of the Consolidated Appropriations Act for mitochondrial replacement therapy research.

As far as lobbying Congress for reconsideration of the ban against mitochondrial replacement therapy goes, the most effective recommendation the FDA could offer as a starting point likely comes in the same form as the original recommendation the expert panel from the National Academies of Sciences made to the FDA in 2016 before the congressional ban was unveiled.[158] This proposal would effectively address the ethical, social, and political issues surrounding mitochondrial replacement therapy in a way that may convince even a Republican Congress to allow preliminary clinical trials to proceed.

First, the panel recommended that federal regulation be implemented, along with principled professional society guidelines to interpret said regulations, to limit any use of mitochondrial replacement therapy strictly to the prevention of life-threatening mitochondrial diseases.[159] This safeguard would assure that research is conducted for the prevention of disease, and would help convince those that misconstrue this technology as analogous with other gene-editing techniques like CRISPR, that this research would not ultimately lead to the ethical melting pot that is "designer babies."

Second, despite the inevitable ethical, social, and political debates associated with research that involves the manipulation and destruction of donated embryos, responsible use of said embryos in clinical research of mitochondrial replacement therapy through ethical frameworks that have already been developed would give at-risk women an opportunity to have genetically related children with a significantly reduced risk of that child having mitochondrial diseases.[160] Despite the unavoidable divide among many people regarding the use of donated human embryos for clinical research, it speaks volumes that a diverse panel of experts in both science and ethics have concluded that at this point it is "ethically permissible to

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(iii) the lack of a specialized authority in charge of reproductive technologies, and (iv) the deeply polarized abortion and 'personhood' debates.").

158 *See* Achenbach, *supra* note 12 (citing INST. OF MED., *supra* note 12).

159 INST. OF MED., *supra* note 12, at 3.

160 *Id.*

conduct clinical investigations of [mitochondrial replacement therapy] subject to certain conditions and principles."[161]

Lastly, the "slow, cautious approach," recommended by the expert committee from the Institute of Medicine and outlined below, is the most reasonable way to address the "ethical, social, and political concerns" many critics of mitochondrial replacement therapy share.[162] Specifically, the aforementioned expert committee maintains that the FDA should begin to consider mitochondrial replacement therapy clinical applications *only when* all health and safety risks are minimized, and the "[l]ikelihood of efficacy is established by preclinical research using in vitro modeling, animal testing, and testing on human embryos *as necessary*."[163] Furthermore, these clinical studies should be limited exclusively to women who are "undisputed[ly]" at risk for transmitting "severe" mitochondrial diseases "characterized by early mortality or substantial impairment of basic function."[164] Additionally, the expert committee proposes limiting initial testing to the gestational transfer of *male* embryos "to prevent potential adverse and uncertain consequences of mitochondrial replacement therapy from being passed on to future generations" via female offspring.[165] Lastly, in order to uphold ethical principles and medical standards, all initial clinical applications should be reserved exclusively to researchers with "demonstrated expertise in and skill with relevant techniques."[166]

CONCLUSION

Regardless of what side of the line one falls on when defining the personhood of an embryo, the ethics of embryonic donation and research, or the future of genetic manipulation and engineering, there is no denying that Congress' premature decision to take a firm stance on these matters through Section 749 of the Consolidated Appropriations Act of 2016 precluded thousands of helpless families

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161 *Id.*

162 *Id.* at 5.

163 *Id.* at 3 (emphasis added).

164 *Id.* at 4.

165 *Id.*; *see* Vogel, *For Boys Only?*, *supra* note 20 ("[T]he panel recommended that only altered male embryos should be used to attempt a pregnancy, to limit the possible risks to future generations . . . [because] [m]ales can't pass along mitochondrial DNA that is altered in the procedure.").

166 INST. OF MED., *supra* note 12, at 3–4.

from pursuing what could turn out to be life-saving technology for their future children. Rather than stand firmly in the sand on what has historically been the Republican ideology towards life and personhood in regards to fetuses and embryos by directly legislating on the matter, Congress controversially and strategically tucked this ban away ever so subtly in a colossal financial bill without leaving any trace as to who actually introduced the ban, or why.

This blatant exercise of partisanship and policy implementation is directly adverse to the purpose of the Appropriations Clause as envisioned by the Framers—a passive check necessary to prevent encroachment on Congress' management of the purse by the executive branch. "Management" of the purse, however, should not be synonymous with complete dictation over the executive branch's ability to use the purse to carry out its own policies and responsibilities. Such tolerance of complete and utter legislative control is a flagrant violation of the separation of powers doctrine that can and will stall progress in a variety of ways. Mitochondrial replacement therapy can prevent thousands of women in the United States from passing along fatal heritable mitochondrial diseases to their children. For now these women are forced to travel to foreign countries to seek any form of medical recourse. This is because, instead of coming to an agreement over the obvious benefits that mitochondrial replacement therapy provides, Republicans and Democrats alike harp over the divergent philosophies towards the research required to get to the finish line.